

CLAIM AMENDMENTS

This listing of claims will replace all prior versions, and listings, of claims in the application.

Listing of Claims

Claim 1 (Previously presented) An oral pharmaceutical dosage form consisting essentially of a H^+ , K^+ -ATPase inhibitor, a gastric antisecretory prostaglandin analogue compound, and optional pharmaceutically acceptable excipients.

Claim 2 (Previously presented) The dosage form according to claim 1 or 40, wherein the dosage form is a tablet formulation.

Claim 3 (Previously presented) The dosage form according to claim 1 or 40, wherein the dosage form is a capsule formulation.

CI Claim 4 (Previously presented) The dosage form according to claim 1 or 40, wherein the H^+ , K^+ -ATPase inhibitor compound is protected by an enteric coating layer.

Claim 5 (canceled)

Claim 6 (Currently amended) The dosage form according to any of claims 1-4 or 40 [[1-5]], wherein the H^+ , K^+ -ATPase inhibitor is omeprazole, an alkaline salt thereof, one of its single enantiomer or an alkaline salt thereof.

Claim 7 (Previously presented) The dosage form according to claim 6, wherein the H^+ , K^+ -ATPase inhibitor is omeprazole magnesium salt.

Claim 8 (Previously presented) The dosage form according to claim 6, wherein the H^+ , K^+ -ATPase inhibitor is S-omeprazole magnesium salt.

Claim 9 (Currently amended) The dosage form according to any of claims 1-4 or 40 [[1-5]], wherein the H^+ , K^+ -ATPase inhibitor is lansoprazole, one of its single enantiomers or a pharmaceutically acceptable salt thereof.

Claim 10 (Currently amended) The dosage form according to any of claims 1-4 or 40 [[1-5]], wherein the H^+ , K^+ -ATPase inhibitor is pantoprazole, one of its single enantiomers or a pharmaceutically acceptable salt thereof.

Claim 11 (Currently amended) The dosage form according to claim 1 or 40, wherein the gastric antisecretory prostaglandin analogue compound is selected from the group consisting of misoprostol, enisoprost, enprostil, one of the single enantiomers thereof or a pharmaceutical acceptable salt thereof.

Claim 12 (Previously presented) The dosage form according to claim 1, wherein the amount of the H^+ , K^+ -ATPase inhibitor is in the range of 1 - 200 mg and the amount of the gastric antisecretory prostaglandin analogue is in the range of 80 - 1000 μg .

Claim 13 (Previously presented) The dosage form according to claim 1, wherein the amount of the H^+ , K^+ -ATPase inhibitor is in the range of 5 - 80 mg and the amount of the gastric antisecretory prostaglandin analogue is in the range of 100 - 800 μg .

Claim 14 (Previously presented) The tableted dosage form according to claim 2, wherein the tablet consists of two different layers, a first layer comprising the H^+ , K^+ -ATPase inhibitor and a second layer comprising the gastric antisecretory prostaglandin analogue.

Claim 15 (Previously presented) The tableted dosage form according to claim 2, wherein the tablet formulation is a multiple unit tableted dosage form comprising:

- a) the H^+ , K^+ -ATPase inhibitor in the form of enteric coating layered pellets,
- b) the gastric antisecretory prostaglandin analogue compound, and optionally
- c) pharmaceutically acceptable excipients,

compressed together into a tablet, wherein the enteric coating layer covering the individual pellets has mechanical properties such that the tableting of the pellets together with the gastric antisecretory prostaglandin analogue and the optional pharmaceutically acceptable excipients does not significantly affect the acid resistance of the enteric coating layered pellets.

Claim 16 (Previously presented) The tableted dosage form according to claim 15, wherein the enteric coating of the individual pellets comprises a plasticized enteric coating layer material.


Claim 17 (Previously presented) The tableted dosage form according to claim 15, wherein the enteric coating layered pellets are further covered with an over-coating layer comprising a film forming polymer and pharmaceutically acceptable excipients.

Claim 18 (Previously presented) The tableted dosage form according to any of claims 15-17, wherein the tablet is divisible.

Claim 19 (Previously presented) The tableted dosage form according to claim 2, wherein at least part of the tablet is in the form of an extended release formulation.

Claim 20 (Previously presented) The tablet dosage form according to claim 19, wherein the part of the tablet giving extended release is a hydrophilic matrix.

Claim 21 (Previously presented) The tablet dosage form according to claim 19, wherein the part of the tablet giving extended release is a hydrophobic matrix.


 Claim 22 (Previously presented) The tablet dosage form according to claim 2, wherein the tablet consists of two different layers, a first layer comprising the H^+ , K^+ -ATPase inhibitor in the form of enteric coating layered pellets compressed with tablet excipients into a layer, and a second layer giving an extended release of the incorporated gastric antisecretory prostaglandin analogue.

Claim 23 (Previously presented) The tableted dosage form according to claim 2, wherein the tablet comprises enteric coating layered pellets of the H^+ , K^+ -ATPase inhibitor layered with a further layer comprising the gastric antisecretory prostaglandin analogue, and the layered pellets are compressed with tablet excipients to form a tablet.

Claim 24 (Previously presented) The tableted dosage form according to claim 23, wherein the pellets before compression to a tablet are covered by a pigmented film coating layer.

Claim 25 (Previously presented) The tablet dosage form according to claim 2, wherein the tablet consists of two types of layered pellets, the first type consisting of enteric coating layered pellets comprising the H^+ , K^+ -ATPase inhibitor and the second type consisting of pellets comprising the gastric antisecretory prostaglandin analogue, wherein all pellets are compressed together with tablet excipients to form a tablet.

Claim 26 (Previously presented) The tablet dosage form according to claim 22, wherein the tablet consists of enteric coating layered pellets comprising the H^+ , K^+ -ATPase inhibitor, and pellets comprising the gastric antisecretory prostaglandin analogue incorporated in a matrix giving an extended release of the prostaglandin analogue.




Claim 27 (Previously presented) The dosage form according to claim 3, wherein the capsule comprises two types of layered pellets, the first type consisting of enteric coating layered pellets comprising the H^+ , K^+ -ATPase inhibitor, and the second type consisting of pellets comprising the gastric antisecretory prostaglandin analogue, and wherein all pellets and the optional pharmaceutically acceptable excipients are filled in the capsule.

Claim 28 (Previously presented) A process for the manufacture of the dosage form according to claim 3, the process comprising the steps of:

- (a) preparing the H^+ , K^+ -ATPase inhibitor in the form of enteric coating layered pellets,
- (b) preparing the gastric antisecretory prostaglandin analogue in the form of pellets coating layered with an extended release film,
- (c) mixing the H^+ , K^+ -ATPase inhibitor pellets with the gastric anti secretory prostaglandin analogue pellets, optionally with pharmaceutically acceptable excipients, and
- (d) filling the mixture into capsules.

Claim 29 (Previously presented) A process for the manufacture of the dosage form according to claim 2, the process comprising the steps of:

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- (a) preparing the H^+ , K^+ -ATPase inhibitor in the form of enteric coating layered pellets,
 - (b) mixing the H^+ , K^+ -ATPase inhibitor with pellets comprising the gastric antisecretory prostaglandin analogue, and optionally with pharmaceutically acceptable tablets excipients, and
 - (c) compressing the mixture into multiple unit tableted dosage forms without causing any significant change of the acid resistance of the enteric coating layered pellets.

Claim 30 (Previously presented) The process according to claim 29, wherein the pellets of the gastric antisecretory prostaglandin analogue are coating layered with an extended release layer.

Claim 31 (Currently amended) A method for the treatment and prophylaxis of gastrointestinal disorders by administering to a host in need thereof a therapeutically effective dosage form according to any of claims 1-4 or 40 [[1-5]].

Claim 32 (Currently amended) A method for avoiding gastrointestinal side-effects normally associated with gastric antisecretory prostaglandin analogue medicament treatment by administering to a host in need thereof a therapeutically effective dosage form according to any of claims 1-4 or 40 [[1-5]]

Claim 33 (Canceled)

Claim 34 (Canceled)

Claim 35 (Original) A combination of a H^+ , K^+ -ATPase inhibitor, a gastric antisecretory prostaglandin analogue and a calcium channel blocking agent in the treatment of gastrointestinal diseases.

Claim 36 (Original) A blister pack comprising a H^+ , K^+ -ATPase inhibitor medicament and a gastric antisecretory prostaglandin analogue medicament.

Claim 37 (Previously presented) The blister pack according to claim 36 comprising an additional medicament which is a calcium channel blocking agent.

Claim 38 (Previously presented) The dosage form according to claim 4, wherein the dosage form further comprises a separating layer applied under the enteric coating, wherein the separating layer separates the H^+ , K^+ -ATPase inhibitor from the enteric coating layer.

Claim 39 (Previously presented) The tableted dosage form according to claim 23, wherein the compressed tablet is covered by a pigmented tablet coat.

Claim 40 (Previously presented) An oral pharmaceutical dosage form consisting essentially of a H^+ , K^+ -ATPase inhibitor, a gastric antisecretory prostaglandin analogue compound, a calcium channel blocking agent and optional pharmaceutically acceptable excipients.